REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks herein, is respectfully requested. Claims 1-42 are pending.

The Examiner rejected claims 28-29, 32 and 34-35 under 35 U.S.C. § 102(b) as being anticipated by Ivanovic et al. (Nature Medicine, 1:282 (1995)). The Examiner also rejected claims 28-32, 34-35 and 37-42 under 35 U.S.C. § 103(a) as being unpatentable over Ivanovic et al. The Examiner further rejected claims 28-29, 33 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Ivanovic et al., and further in view of Kattan et al. (J. National Cancer Institute, 90:766 (1998)). These rejections are respectfully traversed.

Ivanovic et al. compared TGF-β1 levels in plasma from normal patients, patients with benign prostatic hypertrophy (BPH), patients with prostate cancer (CaP) having all or most of their prostate tissue and tumor confined to the prostate (primary stage II) or tumor with extensive extracapsular extension, seminal vesical involvement, lymph node metastases or distant metastases (primary stage III/IV), and patients with secondary stage II or secondary stage III/IV (page 282). It is disclosed that patients having tumors with extensive extracapsular extension, seminal vesicle involvement, lymph node metastases or distant metastases (primary stage III/IV) had a statistically significant increase in TGF-β1 levels in plasma over controls (page 282). Ivanovic et al. admit that it is premature to predict the clinical status of "secondary CaP patients" (those whose blood samples were drawn after radical prostatectomy), but speculate that elevated TGF-β1 levels in those patients may indicate that those patients are at high risk for existing metastatic CaP (page 282).

The Examiner alleges that Ivanovic et al. teach apparatus and processors since TGF-β1 was measured by the PREDICTA TGF-beta1 kit using an EL microplate ELISA reader (page 283). The Examiner is requested to consider that the kit employs labeled antibodies to measure TGF-β1, and the microplate reader measures absorbence which correlates with labeled antibody binding to TGF-β1.

Ivanovic et al. do not teach or suggest an apparatus or method in which software analyzes the level or amount of at least one protein in a physiological fluid sample obtained from a human prostate cancer patient treated for clinically localized prostate cancer and provides the risk of

prostate cancer progression in the patient or the risk of non-prostate confined cancer in the patient.

Accordingly, withdrawal of the § 102(b) and § 103(a) rejections over Ivanovic et al. is respectfully requested.

Kattan et al. disclose a preoperative nomogram for prostate cancer progression. The nomogram is shown in Figure 2 and employs PSA level, clinical stage of the tumor, and biopsy Gleason sum to predict prostate cancer recurrence in patients following radical prostatectomy.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine Ivanovic et al. with Kattan et al. to result in the claimed invention because Kattan et al. adds the ability to plot nomograms in the analysis of the prognosis and assessment of prostate cancer.

However, neither Ivanovic et al. nor Kattan et al. disclose or suggest analyzing the amount or level of TGF-β in a physiological fluid sample from a human prostate cancer patient treated for clinically localized prostate cancer with software that provides the risk of prostate cancer progression in the patient or the risk of non-prostate confined cancer in the patient, or a nomogram that provides the risk of progression or nonprostate confined disease in a prostate cancer patient treated for clinically localized prostate cancer based on factors including TGF-β levels.

Therefore, withdrawal of the § 103(a) rejection over Ivanovic et al. and Kattan et al. is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date September 5, 2006 By

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Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5th day of September, 2006.

Name

Signature